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STATE AND CONSUMERS AFFAIRS AGENCY
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Questions and Answers about Emergency Contraception

In mid-August, the FDA reclassified Plan B from prescription status to over-the-counter status for emergency contraception for male and female buyers aged 18 and older. For patients 17 years and younger, Plan B remains a prescription drug.

In California existing law permits a specially qualified pharmacist to prescribe and dispense emergency contraception, using a variety of drugs, including Plan B (California Business and Professions Code section 4052 and California Code of Regulations section 1746).

The following questions and answers provide guidance to patients and pharmacies.

How does FDA's reclassification of Plan B to over-the-counter status for women 18 and over affect California law?

For women and men age 18 and over, the pharmacy may sell Plan B emergency contraception (EC) without a prescription.

Who may sell Plan B drugs?

The law does not require any specific individual to sell the product – that is a pharmacist, pharmacist intern, pharmacy technician or clerk may sell it.

The directive states that Plan B may only be sold by a pharmacy staffed by a pharmacist. Plan B medication must be stored behind the pharmacy counter.

Does a pharmacist need to consult a patient when selling Plan B?

No, unless in the pharmacist's judgment consultation is warranted.

However, the board considers this to be an important change and an opportunity for pharmacists to assist patients with their understanding of this drug and its correct use. Pharmacists should be alert to any need for patient education and do whatever is needed and appropriate to be sure that patients understand this product.

Does the pharmacist need to keep records of dispensing to women/men over the age 18?

No.

Can a pharmacy sell Plan B to females younger than 18?

Yes, under California Business and Professions Code section 4052, a pharmacist who has completed 1 hour of specific CE and either has a protocol with a prescriber or uses the board's standardized protocol may write a prescription for such a patient and dispense Plan B. The pharmacist may also dispense Plan B to a minor under 18 who requests it.

As a prescription drug – the pharmacist in this case needs to keep a record and to provide consultation. The record must be kept for 3 years.

Is there a cap on the maximum charge a pharmacy may charge for Plan B drugs to a patient 18 and over?

Not in California or federal law.

Is there a cap on the maximum charge a pharmacy may charge for Plan B drugs dispensed to females 17 and younger?

No. A provision that capped the maximum charge at \$10 was repealed once the FDA reclassified the drugs as over-the-counter.

When do the over-the-counter provisions for Plan B take effect?

Once Plan B is re-labeled for over-the-counter use it may be sold without a prescription. The manufacturer believes that this will occur towards the end of 2006.

How does the pharmacy determine whether a purchaser is 18 or older?

If in doubt, check the purchaser's identification.

What if the purchaser lacks the identification?

The pharmacy needs to determine if a purchaser is 18 or older, the same way retailers need to determine whether a customer is 18 for cigarettes or 21 for alcohol sales.

Alternatively, a pharmacy unable to determine whether a purchaser is under 18 may have a qualified pharmacist write a prescription for an EC drug.

The California EC protocol developed by the Board of Pharmacy and Medical Board of California lists a number of other products that can be used for EC and provided by a qualified pharmacist. Are these products now also over-the-counter when used for EC?

No. Only Plan B has been reclassified for over-the-counter use for purchasers 18 and older. The other products listed in the California EC protocol remain prescription items that can be prescribed by a pharmacist according to the protocol provisions.